DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 14, 2014

Covidien
Ms. Nancy Sauer
Regulatory Affairs Product Manager
5920 Longbow Drive
Boulder, Colorado 80301

Re: K141153
Trade/Device Name: LigaSure Sealer / Dividers, Models LF1212A, Precise Plus, LF1637, LF1720, LF1737, LF1744, and LF4318
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: May 19, 2014
Received: May 20, 2014

Dear Ms. Sauer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K141153

Device Name
LigaSure Curved, Small Jaw, Open Sealer/Divider (LF1212A, Precise Plus)

Indications for Use *(Describe)*
The LF1212A LigaSure Sealer/Divider is a bipolar electrosurgical instrument intended for use in open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired. The LigaSure Sealer/ Divider can be used on vessels (arteries and veins) up to and including 7 mm. It is indicated for use in general surgery and in such surgical specialties as urologic, thoracic, plastic, and reconstructive. Procedures may include, but are not limited to, bowel resections, gall bladder procedures, Nissen fundoplication, and adhesiolysis.
The instrument is also indicated for open ENT procedures in adults (thyroidectomy, radical neck dissection, parotidectomy, and tonsillectomy) for ligation and division of vessels, lymphatics and tissue bundles 2-3 mm away from unintended thermally-sensitive structures such as nerves and parathyroid glands.

The LigaSure system has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the LigaSure system for these procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K141153

Device Name
5 mm Blunt Tip Sealer/Divider (LF1637)
Maryland Jaw Sealer/Dividers One Step Sealing (LF1720, LF1737, LF1744)

Indications for Use *(Describe)*

The LigaSure Sealer/Divider is a bipolar electrosurgical instrument intended for use in minimally invasive or open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired. The LigaSure Sealer/Divider can be used on vessels (arteries and veins) up to and including 7 mm. It is indicated for use in general surgery and such surgical specialities as urologic, vascular, thoracic, and gynecologic. Procedures may include, but are not limited to, Nissen fundoplication, colectomy, cholecystectomy, adhesiolysis, hysterectomy, oophorectomy, etc.

The LigaSure system has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the LigaSure system for these procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K141153

Device Name
Impact Curved, Large Jaw, Open Sealer/Divider (LF4318)

Indications for Use *(Describe)*

The LigaSure Sealer/Divider is a bipolar electrosurgical instrument intended for use in open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired. The LigaSure Sealer/ Divider can be used on vessels (arteries, veins, pulmonary arteries, pulmonary veins) up to and including 7 mm. It is indicated for use in general surgery and such surgical specialties as urologic, vascular, thoracic, and gynecologic. Procedures may include, but are not limited to, Nissen fundoplication, colectomy, cholecystectomy, adhesiolysis, hysterectomy, oophorectomy, etc.

The LigaSure system has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the LigaSure system for these procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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## 510(k) Summary

Date summary prepared: 5/19/14

### 510(k) Submitter/Holder

Covidien
5920 Longbow Drive
Boulder, CO 80301

### Contact

Nancy Sauer
Regulatory Affairs Product Manager
Telephone: 303-581-6791
Fax: 303-530-6313
Email: nancy.sauer@covidien.com

### Name of Device

| | |
|---|---|
| Trade Name: | LigaSure™ Tissue Sealer/Dividers |
| Catalog Numbers: | LF1212A, LF 1637, LF1723, LF1737, LF1744, LF4318, LF5544 |
| Common Name: | Bipolar Electrosurgical Instrument |
| Classification Name: | Electrosurgical cutting and coagulation device and accessories (21 CFR § 878.4400, Class II, GEI). |

### Predicate Devices

All of these devices are legally marketed devices, manufactured by Covidien llc. Each instrument serves as its own predicate device. The 510(k) numbers for these devices are listed below.

- K113572: Precise Plus (LF1212A)
- K130744: 5mm Blunt Tip Instrument (LF1637)
- K133338: Maryland Instruments (LF1723, LF1737, LF1744)
- K123444: Impact Instrument (LF4318)

### Device Description

The LigaSure™ Sealer/Dividers are sterile, single-use, hand-held bipolar electrosurgical instruments designed for use with the Covidien electrosurgical generators to ligate (seal) and divide (cut) vessels, tissue bundles, and lymphatics clamped between the jaws, grasping tissue, and blunt dissection during open and minimally invasive general surgical procedures using radio frequency (RF) energy. A hand actuated mechanism allows the user to open and close the instrument jaws. When the instrument jaws are correctly placed over tissue or vessel to be sealed, the user operates a second control to initiate delivery of bipolar energy, which seals the tissue. When the sealing cycle is complete, the user operates a separate control to active a knife, which divides the tissue along the seal line.

### Indications for Use

This 510(k) is for changes to the indications for use of these devices. The indications for use vary slightly among the devices included in this 510(k) premarket notification.

LF1212A:

The LF1212A LigaSure Sealer/Divider is a bipolar electrosurgical instrument intended for use in open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired. The LigaSure Sealer/ Divider can be used on vessels (arteries and veins) up to and including 7 mm. It is indicated for use in general surgery and in such surgical specialties as urologic, thoracic, plastic, and reconstructive. Procedures may include, but are not limited to, bowel resections, gall bladder procedures, Nissen fundoplication, and adhesiolysis.

The instrument is also indicated for open ENT procedures in adults (thyroidectomy, radical neck dissection, parotidectomy, and tonsillectomy) for ligation and division of vessels, lymphatics and tissue bundles 2-3 mm away from unintended thermally-sensitive structures such as nerves and parathyroid glands.

The LigaSure system has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the LigaSure system for these procedures.

LF1637, LF1723, LF1737, LF1744:

The LigaSure Sealer/Divider is a bipolar electrosurgical instrument intended for use in minimally invasive or open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired. The LigaSure Sealer/Divider can be used on vessels (arteries and veins) up to and including 7 mm. It is indicated for use in general surgery and such surgical specialities as urologic, vascular, thoracic, and gynecologic. Procedures may include, but are not limited to, Nissen fundoplication, colectomy, cholecystectomy, adhesiolysis, hysterectomy, oophorectomy, etc.

The LigaSure system has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the LigaSure system for these procedures.

LF4318:

The LigaSure Sealer/Divider is a bipolar electrosurgical instrument intended for use in open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired. The LigaSure Sealer/ Divider can be used on vessels (arteries, veins, pulmonary arteries, pulmonary veins) up to and including 7 mm. It is indicated for use in general surgery and such surgical specialties as urologic, vascular, thoracic, and gynecologic. Procedures may include, but are not limited to, Nissen fundoplication, colectomy, cholecystectomy, adhesiolysis, hysterectomy, oophorectomy, etc.

The LigaSure system has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the LigaSure system for these procedures.

**Technological Characteristics**

The LigaSure™ Sealer/Dividers work in conjunction with Covidien electrosurgical generators. They use bipolar radiofrequency energy to seal tissues, blood vessels, and lymphatics. The devices also use mechanical action to divide tissue along the seal line.

The Advance instrument works in conjunction with Covidien electrosurgical generators to deliver monopolar energy for tissue dissection and creation of openings in organs.

There are no changes in technical characteristics, only a restatement of the indications for use.

**Performance**

Evidence of safety and effectiveness was presented in the previously submitted 510(k)s, which also demonstrated the compatibility of these instruments with the ForceTriad™ Energy Platform. Supporting data obtained from both bench and preclinical testing. Bench testing to support the indications for use of this device family includes:

- Testing in accordance with IEC 60601-1
- Testing in accordance with IEC 60601-2-2
- Mechanical testing such as blade return, grasping performance, jaw temperature, jaw force, button activation force, knife deployment force, lever force, and power curve performance
- Renal and pulmonary vessel burst pressure testing

Preclinical testing for this device family includes:

- Sealing and dividing vessels up to and including 7 mm
- Ability to achieve hemostasis of tissue and vessels
- Ability to fuse tissue bundles
- Thermal spread measurements
- Lymphatic vessel burst pressure
- Chronic animal study to demonstrate that hemostasis is maintained during recovery from surgery and to demonstrate lack of delayed adverse events

**Conclusion**

The previously submitted data remain valid, and the devices with the restated indications for use remain substantially equivalent to the devices with the original indications for use statements.